Remarks

Applicants have amended the title as requested by the Examiner. Claims 2-24 have been cancelled herein or previously without prejudice or disclaimer. Applicants reserve the right to file one or more continuation applications directed to the subject matter encompassed by all canceled claims. Upon entry of the present amendment, claim 1 will be pending.

Formal Matters

Specification Objections

The specification was objected to because "trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology" and because "it contains an embedded hyperlink and/or other form of browser-executable code." *See*, Paper No. 040405, pages 2-3, paragraph nos. 4(a) and 4(b). In response, Applicants note that they will amend the specification to correct all improper trademark usage and delete all embedded hyperlinks upon receiving a notice of allowability for the present application (and prior to, or concurrent with, payment of the issue fee).

The Examiner has requested a new title that is "clearly indicative of the invention to which the claims are directed". *See*, Paper No. 040405, page 3, paragraph no. 4(c). In respect of this request, Applicants have amended the title as recommended by the Examiner to read: "Polynucleotides Encoding Human Secreted Proteins".

Claim Objections

Claims 1-4 were objected to because they make reference to Table 1A. *See*, Paper No. 040405, page 3, paragraph no. 5. Deletion of "Table 1A" from the claims was requested. Applicants note that they have canceled claims 2-4 and have amended claim 1 to remove reference to "Table 1A." Therefore, the objection of claims 1-4 is moot or obviated.

Rejections under 35 U.S.C. §§ 101

The Examiner has rejected claims 1-10, 15-16, and 22 because the invention is allegedly not supported by either a credible, specific and substantial asserted utility or a well-established utility. *See*, Paper No. 040405, page 4, paragraph no. 6. In particular, the Examiner alleges that "[t]here is no specific disease or specific function that is suggested for the polynucleotides or the encoded polypeptides." *Id.*

As an initial matter, Applicants have canceled claims 2-24 without prejudice or disclaimer. Therefore, the rejection of claims 2-24 under 35 U.S.C. § 101 has been rendered moot.

With respect to the remaining rejected claim 1, Applicants respectfully disagree and traverse. Contrary to the Examiner's position, the specification does indeed disclose at least one specific and substantial utility for the claimed invention. Applicants note that the specification teaches that the HODFN71 polynucleotide may be involved in regulating production of TNF alpha, T cells, and IL-2 production. *See* Table 1D, last column, 971-983. Further, the specification teaches that based in part on its ability to regulate immune cell production, the HODFN71 polynucleotide would be useful for diagnosing and/or treating autoimmune disorders (e.g., rheumatoid arthritis and multiple sclerosis) and cancers (e.g., leukemia and lymphoma). *Id.* Therefore, the specification clearly and specifically asserts a biological role for the HODFN71 polynucleotide and correlates this activity to specific autoimmune disorders and cancers. As such, it logically follows that there is at least one patentable use for the polynucleotides of the present invention.

Applicants point out that the specification need only make *one* credible assertion of utility for the claimed invention to satisfy 35 U.S.C. § 101. *See, e.g., Raytheon v. Roper*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. (1983), *cert. denied*, 469 U.S. 835 (1984). The disclosure of the use of HODFN71 polynucleotides for a number of specific disorders does not negate the specificity of any one of these uses. Indeed, the M.P.E.P. at § 2107.02 states "[i]t is common and sensible for an applicant to identify several specific utilities for an invention . . .". Further, "[i]f applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established." *Id. See also In re Malachowski*, 189 U.S.P.Q. 432 (C.C.P.A. 1976); *Hoffman v. Klaus*, 9 U.S.P.Q.2d 1657 (Bd. Pat. App. & Inter. 1988).

Moreover, where the specification discloses a biological activity (e.g., involvement in IL-2 production), and reasonably correlates that activity to a disease condition (e.g., rheumatoid arthritis), the specification has sufficiently identified a specific utility for the invention. M.P.E.P. § 2107.01 at 2100-32 (emphasis added). In other words, so long as the correlation between the biological activity and the asserted use in a particular disease or condition is sufficient to convince one of skill in the art, then the specificity requirement of 35 U.S.C § 101 is satisfied. *See also*, Fujikawa v. Wattanasin, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996). Applicants

submit that, based on the present specification, the ordinary skilled artisan would readily recognize the specific asserted utility of the claimed polynucleotides.

Applicants note that the test for specificity is whether an asserted utility is specific to the subject matter claimed, in contrast to a utility that would be applicable to the broad class of the invention. *See* M.P.E.P § 2107.01 on page 2100-32. Accordingly, the disclosed utility for the HODFN71 polynucleotides discussed above is specific, in that not every polynucleotide is useful for the diagnosis and/or treatment of the above-mentioned disorders.

Furthermore, the Examiner alleges that the claimed invention is not supported by a substantial utility. As discussed above, Applicants assert that based on what is disclosed in the specification, coupled with what was known in the art on the earliest effective priority date of the present invention, it is reasonable that the claimed invention is useful in the diagnosis and/or treatment of certain disorders, and that such uses fulfill an unmet medical need. The M.P.E.P. states, "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." *See* M.P.E.P. § 2107.01(I). Applicants thus assert that the claimed invention is supported by a substantial "real world" utility.

In view of the above, Applicants maintain that a skilled artisan would not reasonably doubt that HODFN71 polynucleotides can be used in diagnosing and/or treating specific autoimmune disorders and cancers. Thus, the presently claimed invention possesses at least one specific, substantial, and credible utility that constitutes a patentable utility under 35 U.S.C. § 101. Because Applicants' assertions of utility are sufficient to satisfy the requirements of 35 U.S.C. § 101, it is respectfully requested that the Examiner's rejection of claim 1 under 35 U.S.C. § 101 be reconsidered and withdrawn.

Rejections of Claims 1-10, 15-16, and 22 under 35 U.S.C. § 112, First Paragraph

A. Enablement

Claims 1-10, 15-16, and 22

Claims 1-10, 15-16, and 22 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. *See*, Paper No. 040405, page 8, paragraph no. 8. More particularly, the Examiner states, "since the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility...one skilled in the art would not know how to use the claimed invention." *Id.*

Applicants have canceled claims 2-10, 15-16, and 22 without prejudice or disclaimer. Accordingly, the rejection with respect to these claims is now moot. With respect to pending claim 1, Applicants respectfully disagree and traverse.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a credible, specific, and substantial utility. Therefore, the Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on 'lack of utility' basis unless a 35 U.S.C. § 101 rejection is proper." M.P.E.P. § 2107(IV) at 2100-28 (Rev. 1, Feb. 2000). Since the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejection of the claim 1 under 35 U.S.C. § 112, first paragraph, based on lack of utility of the claimed invention, should be withdrawn.

Claims 1-10, 15-16, and 22 were also rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because "the claims encompass an unspecified amount of fragments that are not supported by the instant specification" and the "claims reciting percent sequence identity...do not indicate where variations will occur or what variations can be tolerated in the sequence." *See*, Paper No. 040405, page 8, second paragraph.

Applicants note that claims 2-10, 15-16, and 22 have been canceled herein. Accordingly, the enablement rejection with respect to these claims is now moot. Without acquiescence to the present rejection, claim 1 has been amended such that it no longer recites polypeptide fragments or percent identity. Therefore, Applicants submit that the enablement rejection of claims 1 under 35 U.S.C. §112, first paragraph has been obviated. Thus, Applicants respectfully request that the Examiner's rejection of pending claim 1 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

B. Written Description

Claims 1-10 and 15-16 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *See*, Paper No. 040405, page 10, paragraph no. 9.

In particular, the claims were rejected for allegedly lacking written description based on the following issues: 1) the claims are directed to fragments of the claimed nucleic acid and the encoded protein and the claims are absent functional language; 2) the claimed invention

allegedly lacks complete deposit inform tion; 3) the claims are directed to nucleotide sequences that comprise sequential deletions from he C or N terminus and there is no limit on the amount of nucleotides that can be deleted, and o demonstration of any conserved region or the effects of the modifications contemplated; and 4) the claims do not set forth the hybridization conditions that are considered to be stri gent. *Id.* at pages 10-13.

In response, Applicants note that claims 2-10 and 15-16 have been cancelled herein. Furthermore, claim 1 has been amended such that the rejected language has been deleted. Accordingly, the written description rejection with respect to claims 1-10 and 15-16 is now moot or obviated. Thus, Applicants respectfully request that the Examiner's rejection of pending claim 1 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Indefiniteness Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-10 and 15-16 were rejected as indefinite under 35 U.S.C. §112, second paragraph, for "failing to set forth the subject matter, which applicant(s) regard as their invention." *See*, Paper No. 040405, page 13, paragraph no. 10.

Claim 1

Claim 1 was rejected as allegedly indefinite for reciting: 1) full-length polypeptide encoded by the HODFN71 cDNA C ne ID in ATCC Deposit No: 203570 corresponding to SEQ ID NO:421; 2) hybridizing unde stringent conditions; 3) A residues or T residues; and 4) said fragment has biological activity. *See Id.* at 14, first paragraph. In response, Applicants note that claim 1 has been amended to delete the allegedly indefinite language. Accordingly, the rejection to claim 1 has been obviated. Thus, Applicants respectfully request that the Examiner's rejection of claim 1 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

Claim 3

Claim 3 was rejected for reciting "comprises sequential nucleotide deletions" which is allegedly indefinite. *See Id.* at 14, second paragraph. Applicants note that claim 3 has been cancelled herein. Accordingly, the rejection of claim 3 is now moot.

Claims 5 and 6

Claims 5 and 6 were rejected for reciting "is hybridizable to SEQ ID NO:132" which is allegedly indefinite. *See Id.* at 14, penultimate paragraph. Applicants note that claims 5 and 6 have been cancelled herein. Accordingly, the rejection to claims 5 and 6 is now moot.

Claims 15 and 16

Claims 15 and 16 were rejected as allegedly indefinite "because the claims depend from a non-elected claim." *See Id.* at 14, last paragraph. Applicants note that claims 15 and 16 have been cancelled herein. Accordingly, the rejection to claims 15 and 16 is now moot.

Conclusion

Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425.

Respectfully submitted,

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